

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division**

Outsourcing Facilities Association, *et al.*,

Plaintiffs,

v.

U.S. Food and Drug Administration, *et al.*,

Defendants.

Case No. 4:24-cv-00953-P

**JOINT STATUS REPORT AND JOINT MOTION TO REOPEN CASE
AND ENTER SCHEDULING ORDER**

The parties submit this joint status report and motion pursuant to this Court's Orders dated October 11, 2024, ECF No. 28, November 22, 2024, ECF No. 31, and December 26, 2024, ECF No. 33. The October 11, 2024 Order granted Defendants' unopposed motion to voluntarily remand the challenged decision to the United States Food and Drug Administration (FDA) and stayed litigation pending further court order. On December 19, 2024, FDA issued a declaratory order on remand and the parties informed the Court that they would confer regarding next steps in this litigation. ECF No. 32. The Court's December 26, 2024 Order continued the stay and ordered the parties to file a further joint status report by January 2, 2025 highlighting the next steps for this case.

The parties have conferred regarding next steps and propose that the Court reopen the case and set a briefing schedule on Plaintiffs' forthcoming motion for a preliminary injunction. We note two preliminary matters. First, yesterday afternoon, Eli Lilly and Company filed a motion to intervene in this case, ECF Nos. 34, 35, for which the Court has set a briefing schedule, ECF No. 37; the parties' proposed schedule on Plaintiffs' motion for a preliminary injunction does not address any impact Lilly's future intervention might have. Second, Plaintiffs have received a redacted version of FDA's

December 19, 2024 Decision Memorandum that contains third-party confidential information. The parties intend to negotiate an agreed-upon protective order that will allow Plaintiffs to be provided with information that is currently redacted in the Memorandum. The parties will endeavor to file a motion for a protective order by January 15 or earlier if possible and, upon entry of that order, Defendants will provide Plaintiffs with the Memorandum.

The parties propose that deadlines related to Plaintiffs' motion for preliminary injunction will follow Plaintiffs being provided with the Decision Memorandum, as follows:

- Plaintiffs will file their motion for a preliminary injunction two weeks after receiving the Decision Memorandum under a protective order.
- Defendants will file their opposition four weeks after Plaintiffs' deadline or on the first business day thereafter.
- Plaintiffs will file their reply ten days after Defendants' opposition or on the first business day thereafter.
- Defendants' responsive pleading deadline will be stayed pending further Court order.

When Plaintiffs have received the Decision Memorandum under a protective order, the parties will notify the Court and set forth the dates for the deadlines described above. If the Court enters the foregoing schedule and it is adhered to, Defendants will continue to exercise the enforcement discretion described in Defendants' unopposed motion for voluntary remand through the Court's resolution of Plaintiffs' motion for a preliminary injunction. *See* ECF No. 27 at 3.

DATED: JAN. 2, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

January 2, 2025

/s/ Oliver McDonald
OLIVER McDONALD